

Clearinghouse Rule 18-055

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : CONTROLLED SUBSTANCES BOARD
CONTROLLED SUBSTANCES BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.54 relating to scheduling of oral solutions containing dronabinol.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.16, Stats.

Statutory authority: ss. 961.11 (1) and (4), Stats.

Explanation of agency authority:

The controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227. [s. 961.11 (1), Stats.]

If a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30-day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the

board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2). [s. 961.11 (4), Stats.]

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:

On March 23, 2017, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register placing Food and Drug Administration approved products of oral solutions containing dronabinol into Schedule II of the federal Controlled Substances Act.

Plain language analysis:

The Controlled Substances Board did not receive an objection to treating Food and Drug Administration approved products of oral solutions containing dronabinol as a schedule II controlled substance under ch. 961, Stats. based upon the federal scheduling. The Controlled Substances Board took affirmative action on May 12, 2017 to similarly treat Food and Drug Administration approved products of oral solutions containing dronabinol under chapter 961 effective May 15, 2017 to allow for publication in the Administrative Register. The Affirmative Action Order will expire upon promulgation of a final rule.

This rule creates s. 961.16 (10) (a), Stats. which adds Food and Drug Administration approved products of oral solutions containing dronabinol to schedule II.

Comparison with rules in adjacent states:

Illinois: Illinois has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Iowa: Iowa has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Michigan: Michigan has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Minnesota: Minnesota has not scheduled Food and Drug Administration approved products of oral solutions containing dronabinol.

Summary of factual data and analytical methodologies:

The methodology was to schedule Food and Drug Administration approved products of oral solutions containing dronabinol to conform with the federal Controlled Substances Act.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

This rule schedules a drug and does not have an effect on small business.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Kirsten.Reader@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by August 22, 2018 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. CSB 2.54 is created to read:

CSB 2.54 Addition of Oral Solutions containing dronabinol to schedule II. Section 961.16 (10) (a), Stats., is created to read:

961.16 (10) (a) Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in an oral solution in a drug product approved by the U.S. food and drug administration.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)
